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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,340	02/06/2004	Renato Pedrazzi	02508.0095-01000	4496
22852	7590	09/29/2004	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			KIM, SUN U	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/772,340	Applicant(s) PEDRAZZI, RENATO	
	Examiner John Kim	Art Unit 1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-24, 31, 33-35 and 41-46 is/are rejected.
- 7) ☒ Claim(s) 25-30, 32, 36-40 and 47-49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/980,864.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/6/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 22-23 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by English translated copy of WO 98/50091 (hereinafter referred to as WO translation). WO translation teaches a blood purification device comprising electronic control means (9-14) which based on measurements from pressure gauges 27-3'-4' and balances 5-6-7 to steer flows applied by pumps 1-4 including a pump (2) for replacement fluid i.e. infusion liquid wherein replacement fluid is brought by means of pump (2) from receptacle (15) with a flow divider regulating the proportion between the flow of replacement fluid injected into the blood circulation upstream from the filtration means (8) and the flow of replacement fluid injected into the blood circulation downstream from the filtration means (8) (see figure, page 11, 2nd and 4th paragraphs). WO translation further teaches pumps (2, 3) for circulating infusion liquid in pre dilution and post dilution pipes (see figure).

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 24, 31, 33 (independently), 35, 41 (independently), 42, 44, 45 (independently) and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO translation as applied to claim 22 in above paragraph 2, and further in view of U.S. Patent No. 5,762,805 (hereinafter

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referred to as Truitt et al). WO translation teaches the blood purification device as described in above paragraph 2. Claims 24, 31, 33 (independently), 35, 41 (independently), 42, 44, 45 (independently) and 46 essentially differ from the device of WO translation in reciting monitoring transmembrane pressure values and the actual permeability of a membrane of a filter. Truitt et al teach a device for extracorporeal purification of blood comprising a blood filtration unit (40) comprising pressure sensors (51, 53, 54, 84) for measuring transfilter pressure or transmembrane pressure i.e. a parameter influenced by the resistance of the filtration unit (40) to the flow of liquid (see figures 1-2, col. 3, line 59 - col. 6, line 20), a computation unit comprising a control unit (102) connected to a monitor unit (104) for monitoring pressure sensors (51, 53, 54, 84) and for controlling a pump (66) for controlling the substitution solution to flow in a connecting conduit (70) (see figures 3a-3b, col. 6, line 43 - col. 11, line 40) wherein the control processor (122) in the control unit (102) receives signals from the monitor processor (140) in the monitor unit (104) and transmits signals to a motor controller (128) to halt a pump (66) whenever pressure sensors (51, 53, 54, 84) signal an abnormal pressure value from predetermined stored pressure value and allows operator to adjust the treatment steps to continue the treatment (see col. 17, line 31 - col. 18, line 27; col. 16, lines 10-40). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to incorporate pressure sensors of Truitt et al to measure transfilter pressure which indirectly measures the permeability of the filter in the device of WO translation to improve the control of infusion of liquid.

5. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO translation in view of Truitt et al as applied to claim 33 in above paragraph 4, and further in view of WO 00/09182 (hereinafter referred to as WO '182). WO translation in view of Truitt et al teaches the

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blood purification device as described in above paragraph 4. Claim 34 essentially differs from the device of WO translation in view of Truitt et al in reciting a valve means for alternatively occluding the pre-dilution pipe and the post-dilution pipe. WO '182 teaches a blood purification device comprising valves (3, 4) for controlling the fluid to upstream and downstream of the filter (see abstract; figure 7). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to incorporate valves of WO '182 to control the flow of fluid into the pre dilution pipe and the post dilution pipe in the device of WO translation in view of Truitt et al.

6. Claims 25-30, 32, 36-40 and 47-49 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-1142. The examiner can normally be reached on weekdays from 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (571) 272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John Kim
Primary Examiner
Art Unit 1723

J. Kim
September 28, 2004